#### INFORMED CONSENT AND RESEARCH AUTHORIZATION

# Evaluation of a disposable flexible bronchoscope, a randomized, controlled, cross-over trial

IRB assigned number:

Investigator(s) name, & address: Dr. Lenhardt, Rainer, M.D.,

University of Louisville Hospital 530 South Jackson Street

Louisville, KY 40202

Site(s) where study is to be conducted:

University of Louisville Hospital

530 South Jackson Street

Louisville, KY 40202

Phone number for subjects to call for questions: (502) 852-3122/ (502) 478-1155

#### Introduction

You are invited to take part in a research study because you are scheduled to have a bronchoscopy. The study is being conducted under the direction of Rainer Lenhardt, MD at the University of Louisville. About 40 local subjects will be invited to take part in this research. Your participation in the study will last for the time needed to complete the bronchoscopy.

# **Purpose**

Bronchoscopy is a procedure that allows your doctor to look inside your lungs and airways. The airways carry air to the lungs.

During the procedure, your doctor inserts a thin, flexible tube called a bronchoscope into your mouth. The tube is passed down your throat into your airways. If you have a breathing tube, the bronchoscope can be passed through the tube to your airways. You'll be given medicine to make you relaxed and sleepy during the procedure.

The bronchoscope has a light and small camera that allow your doctor to see your windpipe and airways and take pictures. The bronchoscope can also be used to suction fluid and other secretions from the lungs.

This study will compare two types of bronchoscopes. Currently most bronchoscopes are reusable (non-disposable). They are cleaned between uses and also have a disposable single-use shield that covers the bronchoscope.

The aScope 3 is a new option for bronchoscopes. This bronchoscope is for single use and disposable.

This study will compare how well each bronchoscope works. The study team will compare how each scope handles, suctions, and the quality of the camera images.

#### **Procedures**

You will be assigned to one of two groups for the study. One group will start the bronchoscopy procedure with the aScope 3 and then switch to the non-disposable bronchoscope. The other group will start with the non-disposable bronchoscope and then switch to the aScope 3.

During the bronchoscopy, your study doctor will use the aScope 3 for inspection of one side of your lungs and the non-disposable bronchoscope to inspect the other side of your lungs. During the bronchoscopy the study doctor will inspect your airways and lungs and clean them by suction if needed. The Dr. will also put some saline into the lungs and suction it out. This fluid will be collected for testing.

After the procedure, you will have a chest X-ray to make sure the lungs have not collapsed (pneumothorax).

The bronchoscopy procedures and the X-ray are standard procedures. The only difference in the procedure for this study is using two types of bronchoscopes. The study team will be comparing how well each type of bronchoscope performs.

#### Potential Risks.

Bronchoscopy is a well-tolerated procedure. The risks for the study are the same risks you would have with the standard bronchoscopy.

The risks associated with bronchoscopy are:

# Most Common – (1-5%)

- Fever 5%
- Bronchospasm a sudden spasm of the muscles in the airways which can lead to difficulty breathing - less than 1%

# <u>Rare</u>

- Bleeding
- Pneumothorax (collapse of the lung)

# Other Possible Risks

- Contamination or infection due to insertion of the bronchoscope.
- Decrease in oxygen levels -If this occurs, the bronchoscopy will be interrupted to allow the lungs to recover. Occasionally, the procedure may have to be stopped.

#### **Benefits**

The information collected may not benefit you directly; however, the information learned in this study may be helpful to others.

#### **Alternatives**

Instead of taking part in this study, you could choose to not participate.

# **Research Related Injury**

If you are injured by being in this research study, the study doctor will arrange for you to get medical treatment. Study site, or your study doctor has not set aside money to pay for treatment or any injury. You and your insurance will be billed for the treatment of these injuries. Before you agree to take part in this research study you should find out whether your insurance will cover an injury that occurs while participating in research. You should talk to the study doctor or staff about this. If you are injured, there is no money set aside for lost wages, discomfort, disability, etc. You do not give up your legal rights by signing this form. If you think you have a research related injury, please call Dr. Rainer Lenhardt at 502-852-3122.

#### Compensation

You will not be compensated for your time, inconvenience, or expenses while you are in this study.

#### Costs

If you are injured by the research, there may be additional cost for participating in the research. Otherwise there will be no additional cost to you.

#### **HIPAA Research Authorization**

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides federal safeguards for your protected health information (PHI). Examples of PHI are your name, address, and birth date together with your health information. PHI may also include your medical history, results of health exams and lab tests, drugs taken and results of this research study. Your PHI may not be used or shared without your agreement, unless it meets one of the HIPAA exceptions.

State and federal privacy laws protect your health information. In most cases, health information that identifies you can be used or shared by the research team only if you give your permission by signing this form.

If you sign this form your health information will be used and shared to answer the research questions described above and to make sure that the research was done correctly. The time period when information can be used or shared ends when all activities related to this study are completed.

Your access to your health information will not be limited during this study When the study is over, you will have the right to see your health information related to this research.

You do not have to sign this form. If you do not sign this form you may not participate in the study and health information that identifies you will not be shared with the research team.

Your medical treatment is not conditioned upon this authorization, but your research participation is.

# Site(s) where health information about you will be used or shared for this research:

In our research, the research team will look at and may share information about you and your health. Federal law requires that health care providers and researchers protect the privacy and security of health information that identifies you. We may ask for your health information from the following:

#### **Affiliated Sites:**

University of Louisville (Do not delete this site.)
University of Louisville Hospital/J. Graham Brown Cancer Center

# Protected health information (PHI) that will be used or shared for research

Healthcare provider orders
History and physical exams
Laboratory, x-ray, and other tests
Medical progress notes

#### **Revocation of Research Authorization**

You may cancel the permission you have given to use and share your protected health information at any time. This means you can tell us to stop using and sharing your protected health information. If you cancel your permission:

- We will stop collecting information about you.
- You may not withdraw information that was collected before you told us to stop.
  - We may already have used it or shared it.
  - We may need it to complete the research.
- Staff may ask your permission to follow-up with you if there is a medical reason to do so.

To cancel your permission, you must complete a written "Revocation of Research Authorization" form located at the end of this document. You may also obtain a copy from your study doctor, designated personnel or from the Human Subjects Protections Program Office website (http://louisville.edu/research/humansubjects/subject-information).

# Information Available on ClinicalTrials.gov

A description of this clinical trial will be available on <a href="http://www.ClinicalTrials.gov">http://www.ClinicalTrials.gov</a>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

# Confidentiality

Total privacy cannot be guaranteed. We will protect your privacy to the extent permitted by law. If the results from this study are published, your name will not be made public. Once your information leaves our institution, we cannot promise that others will keep it private.

Your information may be shared with the following:

- The University of Louisville Institutional Review Board, Human Subjects Protection Program Office, Privacy Office and others involved in research administration at the University
- The local research team
- People who are responsible for research and HIPAA oversight at the institutions where the research is conducted
- People responsible for billing, sending and receiving payments related to your participation in the study
- Government agencies, such as:
  - Office for Human Research Protections
  - Office of Civil Rights
  - Food and Drug Administration

# Security

Your information will be kept private by storing all data about you on a encrypted computer that is password protected. Any paper data sheets will be stored in locked cabinet in the Department of Anesthesiology or at the UL-ACT office.

# **Voluntary Participation**

Taking part in this study is completely voluntary. You may choose not to take part at all. If you decide not to be in this study, you won't be penalized or lose any benefits for which you qualify. If you decide to be in this study, you may change your mind and stop taking part at any time. If you decide to stop taking part, you won't be penalized or lose any benefits for which you qualify. You will be told about any new information learned during the study that could affect your decision to continue in the study.

#### **Termination**

Your study doctor has the right to stop this study at any point. Your study doctor may take you out of this study with or without your okay. Reasons why this may occur include: you are experiencing another health condition that needs immediate attention.

# **Participation in Other Research Studies**

You may take part in this study if you are currently in another research study. It is important to let your doctor know if you are in another research study.

#### **Contact Persons**

If you have any questions, concerns, or complaints about the research study, please contact Dr. Rainer Lenhardt at (502) 852-3122 or (502) 478-1155 (this is a pager number). Please enter your phone number and someone will return your call)

# Research Subject's Rights

If you have any questions about your rights as a research subject, you may call the Human Subjects Protection Program Office at (502) 852-5188. You may discuss any questions about your rights as a research subject, in private, with a member of the Institutional Review Board (IRB). You may also call this number if you have other questions about the research, and you cannot reach the study doctor, or want to talk to someone else. The IRB is an independent committee made up of people from the University community, staff of the institutions, as well as people from the community not connected with these institutions. The IRB has approved the participation of human subjects in this research study.

# **Concerns and Complaints**

If you have concerns or complaints about the research or research staff and you do not wish to give your name, you may call the toll free number 1-877-852-1167. This is a 24-hour hot line answered by people who do not work at the University of Louisville.

# **Acknowledgment and Signatures**

This informed consent document is not a contract. This document tells you what will happen during the study if you choose to take part. Your signature indicates that this study has been explained to you, that your questions have been answered, and that you agree to take part in the study. You are not giving up any legal rights to which you are entitled by signing this informed consent document. You will be given a copy of this consent form to keep for your records.

Subject Name (Please Print)	Signature of Subject	Date Signed
Printed Name of Legal Representative (if applicable)	Signature of Legal Representative	Date Signed
Relationship of Legal Representative to Subject		
Printed Name of Person Explaining Consent Form	Signature of Person Explaining Date Signed Consent Form (if other than the Investigator)	

Printed Name of Investigator	Signature of Investigator	Date Signed		
List of Investigators:	Phone Numbers:			
Rainer Lenhardt,M.D.	(502) 852-3122			
Ozan Akca, MD Rana Latif, MD Forest Arnold, DO Julio Ramirez, MD Rodrigo Cavallazzi, MD	(502) 852-1739 (502) 852-8144 (502) 852-7844 (502) 852-5131			
Study Staff:				
Elizabeth Cooke, R.N.	(502) 852-8016			

# REVOCATION OF AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR HEALTH INFORMATION FOR RESEARCH

PI Address: 530 South Jackson Street Louisville, KY 40202 PI Phone: (502) 852-3122	Return To: OR	Institutional Review Board MedCenter One, Suite 200 501 E. Broadway Louisville, KY 40202
Do not sign this letter unless you are w sent confirmation that this notice was	_	g from this research. You will be
To Whom It May Concern:		
I would like to discontinue my participation in the information already collected will continue to be uthe study.		
Your options are ( <i>choose one</i> ):		
☐ Withdraw from Study & Discontinue Autho	orization:	
Discontinue my authorization for the future us instances, the research team may need to us authorization, for example, to notify you or go identified as part of your study participation.	e your informa	•
☐ Withdraw from Study, but Continue Autho	rization:	
	of the study a	from my personal health information. This would and would not be used for purposes other than
Printed Name and Signature of Subject		Date Signed
Signature of Subject's Legal Representative (if su	ubject is unabl	ole to sign) Date Signed
Printed Name of Subject's Legal Representative		Birthdate of Subject
Relationship of Legal Representative to Subject		
Subject's Address		Subject's Phone Number
<b>Optional:</b> I am ending my participation in this study because	e:	

Page 8 of 8